UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,666	12/08/2003	Leah Marie Gayo-Fung	10624-136-999	6368

20583 7590 03/07/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,666	GAYO-FUNG ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 34-39 is/are pending in the application.

4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 34-39 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/8/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment (Filed 08 December 2003) cancelled claims 1-33 and 40. Claims 34-39 were amended. Claims 34-39 are pending and examined.

Claims 34-39 are pending.

Claims 34-39 are rejected.

Information Disclosure Statement

The information disclosure statement (IDS) submitted December 08, 2003 has been acknowledged.

Abstract

The abstract is objected to because of the following informalities: The abstract should only contain one period. However, it is noted to have several periods. Appropriate correction is required - ? this is ok Abstracts are composed of multiple complete sentences but can only be one (1) paragraph.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 34-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 49 of U.S. Patent No. 6,436923 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims refer to the same compounds (see patented claims 1-49) and using the compound (see claim 34 in the current application) modulating ER-β in a cell. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 34-39 and patented claims 1-49. The compositions recited in the claims are anticipatory of each other.

As to the patented claims 1-49, these claims refer to a process of making a compound. Thus, the process of making is a set of precursor steps to the process of modulating ER-β in a cell with an effective amount of the compound recited in the patented claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

II. Claims 34-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,686,351 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims refer to the same compounds (see patented claims 1-17) and using the compound (see claim 34 in the current application) modulating ER-β in a cell. The current application claims anticipate the patented claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 34-39 and patented claims 1-17. The compositions recited in the claims are anticipatory of each other.

As to the patented claims 1-17, these claims refer to a process of making a compound. Thus, the process of making is a set of precursor steps to the process of modulating ER-β in a cell with an effective amount of the compound recited in the patented claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

III. Claims 34-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,372,739 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims refer to the same compounds (see patented claims 1-20) and using the compound (see claim 34 in the current application) modulating ER-β in a cell. The current application claims anticipate the patented claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 34-39 and patented claims 1-20. The compositions recited in the claims are anticipatory of each other. In view of the foregoing, the copending application claims and the current application claims are obvious variations.

IV. Claims 34-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent co-

pending application No. 10/085995. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims refer to the same compounds (see co-pending application claims 34-39) and using the compound (see claim 34 in the current application) and claim 1 of the co-pending application for modulating ER-β in a cell. The current application claims anticipate the copending application claims. Both applications recite using the same compositions and/or derivatives thereof. See current application claims 34-39 and patented claims 1-44. The compositions recited in the claims are anticipatory of each other. In view of the foregoing, the copending application claims and the current application claims are obvious variations.

V. Claims 34-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-78 of U.S. Patent No. 6291456. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims refer to a method of modulation using (see patented claims 34-78) and (claims 34-39) in the current application. The current application claims anticipate the copending application claims. Both applications recite using the same compositions and/or derivatives thereof. See current application claims 34-39 and patented claims 36-78. In view of the foregoing, the copending application claims and the current application claims are obvious variations.

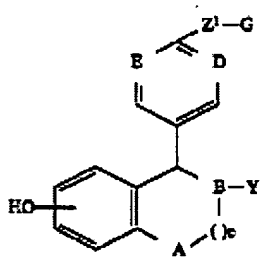
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

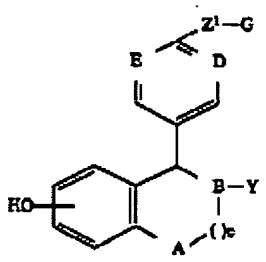
Claims 34- 37 and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron et al US 5,552,412

Cameron et al disclose compounds with the core structure



recited in claim 34 as having estrogenic properties (see abstract). The "a" in the claimed invention is an equivalent to "e" in the patented claims e =1 (see col. 10 line 41), A, B and C = represent D, B and E =CH (see col. 10 lines 41+), Y =R_2 is a six membered-heterocycle ring (see col. 4 lines 50+), R_3 is hydrogen (see col. 4 lines 20-30). The patent the reference anticipates the claimed invention of instant claims 34, 37 and 38. With regard to the use in modulating ER-β in a cell

Cameron discloses the compound to be –



(see abstract).

Modulating ER-β in a cell expressing ER-β – does not alter the compound or the composition. Consequently, the reference anticipates the claimed invention defined in claims 34, 37 and 38.

With regard to claims 36 and 39, Cameron discloses treating breast cancer, bone disease (osteoporosis) (see col. 8 lines 9-15). Absent factual evidence it is anticipated in-order for the treatment to occur the compound is in contact with the cell.

Claim Rejections - 35 USC § 103

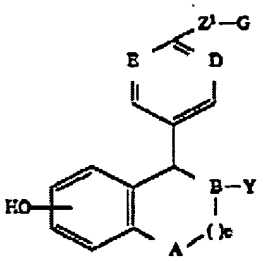
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

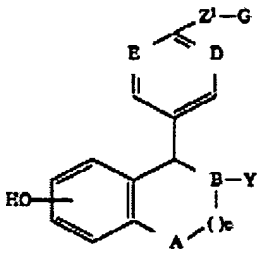
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron et al US 5,552,412 in view of Stein et al., US 6,291,456 B1.

Cameron et al teach compounds with the core structure



recited in claim 34 as having estrogenic properties (see abstract). Where, a in the claimed invention is an equivalent to e in the patented claims e =1 (see col. 10 line 41), A, B and C = represent D, B and E =CH (see col. 10 lines 41+), Y =R_2 is a six membered heterocycle ring (see col. 4 lines 50+), R_3 is hydrogen (see col. 4 lines 20-30). Subsequenly as disclosed in the patent the reference anticipates the claimed invention of instant claims 34, 37 and 38. With regard to the use in modulating ER-β in a cell Cameron teaches the compound to be –



(see abstract).

Modulating ER-β in a cell expressing ER-β – does not alter the compound nor the composition. Consequently, the reference is an obvious over the claimed invention defined in claims 34, 37 and 38.

With regard to claims 36 and 39, Cameron teach treating breast cancer, bone disease (osteoporosis) (see col. 8 lines 9-15). Absent factual evidence it is anticipated inorder for the treatment to occur the compound is in contact with the cell.

Stein et al teach compounds that modulate estrogen receptors in cells expressing ER-β having the same core structure and substituents of the claimed compound in claim 34 (see abstract). Stein also teaches high level of ER-β is expressed in the ovaries, prostates and brain.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cameron et al with that of Stein et al as both teachings are directed totreating or modulating estrogen expression in cells administering (in-vivo) or contacting the cell (in vitro) with the same compound. It would have been obvious to the skilled artisan (a biochemist in cancer research) that ER-β is highly expressed in ovarian cancers, prostates or hypothalamus, therefore would have administered the drug to inhibit over expression.

One of ordinary skill in the art would be motivated to use the compound (see supra) since it is found to be a member of the a group of estrogen regulator and expect a successful result, because it is known in the art and has been used before the claimed invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
3/4/06

Christopher S. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600